K041105

JUL 2 8 2004

ADMINISTRATIVE INFORMATION

Manufacturer Name:	MacroPore Biosurgery, Inc. 6740 Top Gun Street San Diego, CA 92121
Official Contact:	Kenneth K. Kleinhenz Director of Regulatory Affairs Telephone (858) 458-0900 Fax (858) 458-0994

DEVICE NAME

Classification Name:	Appliance, Fixation, Spinal Intervertebral Body
Trade/Proprietary Name:	MacroPore Hydrosorb Spine System

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 888.3060 Appliance, Fixation, Spinal Intervertebral Body devices intended for use in spinal plating procedures are classified as Class II. They have been assigned Product Code KWQ.

INTENDED USE

The MacroPore Hydrosorb Spine System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

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Design Characteristics

The MacroPore Hydrosorb Spine System is a resorbable graft containment system composed of various sized porous plates / sheet, non-porous plates / sheets, and associated fixation screws manufactured from polylactic acid (PLA). The MacroPore Hydrosorb Spine System is composed of MacroPore Sheets, Plates, and Screws provided with and without USP barium sulfate beads (18mg – 20mg/bead) imbedded into the PLA polymer for radiopacity. MacroPore Sheets and Plates can be cut with scissors to the desired shape and size. The MacroPore Power Pen can also be used to cut or shape the MacroPore Plates / Sheets to the desired shape or size. The MacroPore Sheet and Plates are fully malleable when heated to approximately 55°C (for example, by the use of sterile hot water), and thus can be conformed three dimensionally to most any anatomical orientation.

Screws range in size from 2.4mm to 6.5mm in outer diameter with lengths ranging from 4mm to 30mm. The MacroPore Sheets and Plates are provided in various sizes ranging from 1.0mm to 5.0mm in thickness according to the region to be treated. The MacroPore Sheets and Plates range in size from as small as 24mm x 18mm to as large as 100mm x 100mm. The MacroPore Sheets and Plates are provided with and without macroporous holes. The macroporous holes range in size from 500 microns to 3,000 microns in diameter. The radiopaque barium sulfate beads have an approximate nominal mass of 18mg – 20mg and range in size from 0.5mm – 2.0mm in diameter. All configurations are to be within a mass of 100 grams of polymer.

Various manual instruments (screw drivers, taps, drill bit, etc.) are used in conjunction with the MacroPore Hydrosorb Spine System to assist in the installation process.

Material Composition

The Hydrosorb Spine System is fabricated from polylactic acid (PLA).

In Vitro Testing

Because the MacroPore Hydrosorb Spine Plates / Sheets are intended to be heated in the surgical suite to temperatures above the material's glass transition temperature to facilitate shaping to anatomic structures, testing was performed to determine the effect of prolonged heating in saline at 60°C on inherent viscosity. The testing demonstrates that viscosity stayed within an appropriate range over 120 minutes. Therefore, the relatively brief exposure anticipated during the surgical preparation of Hydrosorb Spine Plates / Sheets is not expected to have a significant effect on its mechanical properties.

Aging studies were performed on MacroPore Hydrosorb Spine System components. Testing demonstrated that the MacroPore Hydrosorb Spine Sheet is as rigid and as strong as the predicate after 6 month of exposure. Mechanical testing was performed on the MacroPore Hydrosorb Spine Sheets and MacroPore Hydrosorb Spine Screws. Testing determined the MacroPore Hydrosorb Spine System to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

Crystallinity was tested for by DSC (differential scanning calorimetery). This test measures the amount of heat energy that is absorbed by a material. A crystalline material will require more energy once it reaches it's melting point. This release of heat energy can be seen on a graph as a sharp spike and is referred to as a "melting endotherm". The tests ran on the sterile and non-sterile samples revealed no endothermic spikes, indicating that the implants are amorphous and non-crystalline.

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EQUIVALENCE TO MARKETED PRODUCT

The MacroPore Hydrosorb Spine System shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: MacroPore OS Spinal System (K010911), the DePuy AcroMed BowTi Anterior Buttress Staple System (K021039), Exactech Tecres Cemex (K000943), and the Bryan Biotrace Model 1730 (K002063); Class II medical devices that were cleared for marketing in the United States.

Indications For Use

The MacroPore Hydrosorb Spine System shares identical indications for use with the predicated devices; MacroPore OS Spinal System (K010911) and the DePuy AcroMed BowTi Anterior Buttress Staple System (K021039) while sharing indications for use principles with the Exactech Tecres Cemex (K000943) and the Bryan Biotrace Model 1730 (K002063) as they are both indicated for use as a radiopaque additive in bone repair procedures.

Design and Materials

The physical designs of the MacroPore Hydrosorb Spine System and the predicate devices [MacroPore OS Spinal System (K010911), and the DePuy AcroMed BowTi Anterior Buttress Staple System (K021039)], are substantially equivalent as they all utilize a solid plate or sheet that is secured in place with screws. The MacroPore Hydrosorb Spine System and the MacroPore OS Spinal System (K010911) predicate are constructed from the same resorbable raw material. The physical design of the MacroPore Hydrosorb Spine System is substantially equivalent to the DePuy AcroMed BowTi Anterior Buttress Staple System (K021039) with respect to a screw sizes up to 6.5mm in diameter. The design features of the MacroPore Hydrosorb Spine System are substantially equivalent to the MacroPore OS Spinal System (K010911) predicate device as both devices utilize flat sheet designs of similar shapes and sizes containing multiple holes that accept a screw. The MacroPore Hydrosorb Spine System and the predicate MacroPore OS Spinal System (K010911) are substantially equivalent as the holes in both of the respective products' plate / sheet devices contain a counter sink feature that assures precision engagement between the plate and the screw. The counter sink design of both the MacroPore Hydrosorb Spine System sheets and the predicate device's sheets share the feature of allowing the screw to be flush with the surface of the plate when properly installed. The counter sink design of both the MacroPore Hydrosorb Spine System sheeting and the predicate device's sheets also share the feature of assuring maximum contact between the screw and sheet as the tapered regions of the sheet and screw neck are designed to engage for maximum contact. The mechanical characteristics of the MacroPore Hydrosorb Spine System are substantially equivalent to the predicate device as the MacroPore Hydrosorb Spine System has the same or greater mechanical strength than the MacroPore OS Spinal System predicate (K010911). The materials used in both the MacroPore Hydrosorb Spine System and the predicate device are identical as both devices are fabricated from the same polylactic acid raw material.

The physical designs of the MacroPore Hydrosorb Spine System and the Exactech Tecres Cemex (K000943) and the Bryan Biotrace Model 1730 (K002063) predicate device are substantially equivalent as they both utilize irradiation sterilized USP barium sulfate in combination with a bone repair device. The barium sulfate beads utilized in the MacroPore Hydrosorb Spine System are fabricated from the identical USP grade barium sulfate as the Exactech Tecres Cemex (K000943) and the Bryan Biotrace predicate device (K002063). The MacroPore Hydrosorb Spine System utilized a maximum amount of 0.3grams of barium sulfate (16 beads) while the predicate devices utilize as much as 5-10 grams of barium sulfate in a single procedure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2004

Mr. Kenneth K. Kleinhenz
Director of Regulatory Affairs
MacroPore Biosurgery, Inc.
6740 Top Gun Street
San Diego, California 92121

Re: K041105
Trade/Device Name: MacroPore Hydrosorb Spine System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: April 26, 2004
Received: April 30, 2004

Dear Mr. Kleinhenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

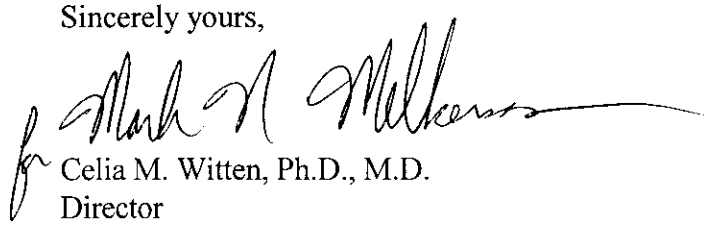
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use:
The MacroPore Hydrosorb Spine System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

for Mark N Milhem

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041105